



Serialized Product Intelligence

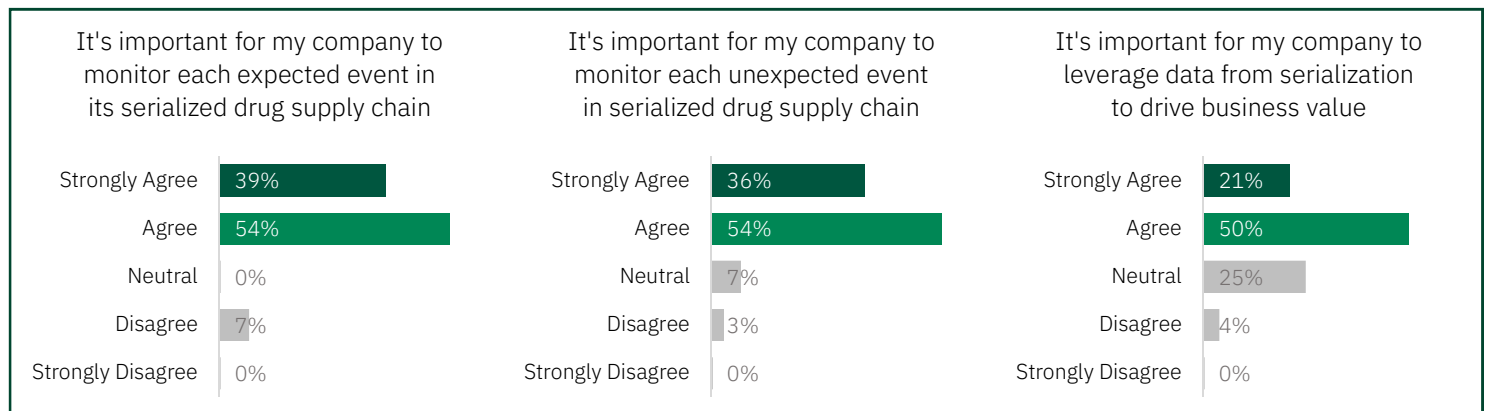
Shift from a Reactive to a Proactive Serialized Supply Chain

Take Control of Your Serialized Supply Chain and Unlock the Value of Serialization Data

By the end of 2020, 80% of global pharma products will be serialized. Serialized medicines are the new normal for the global pharmaceutical industry, and they're a powerful weapon in the fight against drug counterfeiting and diversion.

However, serialization creates enormous complexity and new sources of preventable supply chain disruption, making it difficult to take control of your serialized operations, achieve continuous compliance, meet operational excellence goals, and unlock the value of your serialization data. Moreover, serialization inconsistencies can have a reverberating effect well beyond compliance teams, as these can delay or prevent the delivery of life-saving medicines to patients in need. Yet, while serialization is a considerable effort, it does not have to continuously hold up your organization and divert attention from your core business. In fact, companies have the opportunity to make serialization valuable for all stakeholders.

The benefits of serialization go beyond helping you meet regulatory requirements. In 2020, Tracelink conducted an industry benchmark survey. Over 90% of respondents felt the need to monitor expected and unexpected events in their serialized drug supply chain, and over 70% saw the business potential of serialization data. These organizations see the value in taking control of the serialized supply chain and the potential to drive value across the enterprise. With serialization data, you are sitting on a gold mine waiting to be tapped.



2020 Industry Benchmark by Tracelink: Serialization Program Assessment

The scale of the serialization challenge is different for each enterprise – from launching a critical stock keeping unit (SKU) to having a high-volume multi-SKU business. You may be expanding into several markets or launching your first product in a single country. Either way, conventional efforts to control the serialized supply chain and uncover insights from serialization data can be daunting and involve downloading massive quantities of disparate data from various sources, combining, and analyzing them. It is a manual, time consuming, and error prone process. Even then, data remain in the confines of distributed systems, with limited context.

Meet Serialized Product Intelligence

TraceLink Serialized Product Intelligence™ (SPI) is a new cloud application that provides actionable intelligence for your serialized drug supply chain. It enables a pharma company to proactively monitor the serialized drug supply chain, accelerate the resolution of inconsistencies, and strive for timely product delivery to the market.

Serialized Product Intelligence Capabilities

SPI helps you monitor operations proactively and take control of the serialized supply chain. You can search, query, and examine serialization data at various levels of granularity in the right context. This aids in gaining visibility across the serialized supply chain. SPI helps you shift from fire-fighting mode to operational excellence by sustaining serialization and streamlining operations.



Review Serial Number Events

- Analyze item movement time series data reported to TraceLink, significantly reducing root cause analysis time
- Conveniently view all compliance and serialization events
- Analyze products, serial numbers, and events associated with transactions such as shipments or receipts
- Compare operational events with regulatory reports to verify accuracy or troubleshoot
- View compliance failures and drill into the root causes



Reconcile Serial Numbers

- Have a consolidated view of the most current status of items in a lot, inside a pallet, or sent in the last transaction
- Gain visibility into serial numbers by their status (commissioned, shipped, damaged, sampled, blocked, destroyed, etc.)
- See by the most current aggregation hierarchy reported to TraceLink
- Compare TraceLink data with ERP/Level 3 systems easily



Monitor Commissioned Lots

- View all manufactured products on a single screen
- Monitor actual commissioned and aggregated quantities across CMOs
- Validate aggregation accuracy
- Enable stakeholders to review production in self-service manner without relying on serialization IT and service tickets, e.g., a product country P&L owner can now review if production is on track for their target markets



Review Messages¹

- Monitor messages by business transaction and message type
- View summarized message successes and failures
- Easily drill into message details to understand the reason behind a message failure



Search Audit Trail¹

- Have a lateral view into entire serialization operations with previously untapped valuable audit trail information
- Monitor audit trail across users, systems and events by TraceLink application
- Drill into specific audit details to examine who changed what data when
- Equip your quality staff to efficiently monitor and demonstrate compliance to FDA CFR 21.11 and EU Annex 11

Event-Level Visibility	Serial-Number-Level Visibility	Lot-Level Visibility	Message Exchange Visibility	System and User Action Visibility
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SPI Capabilities for Actionable Intelligence

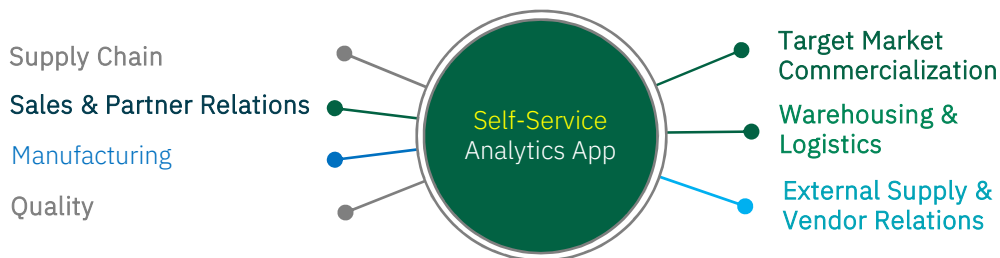
Visibility into your serialized operations matters more than ever – for better control of your supply chain and for medicine availability. SPI provides such visibility to help you move beyond fighting fires every day. You can harness insights from serialized data across the value chain at different granularity levels to catch issues early. If products get held up in transit, a faster root cause analysis and timely action keep the supply chain and the business moving. When it is time for an audit, you can show that there are no errors of omission and every action of users and systems is recorded and tracked.

Maintaining smooth serialized operations keeps your boat steady – while you adjust the sails with the benefit of a transparent supply chain. With operations on track, you can focus your attention on scaling your business, launching new products, and driving brand reliability, without a repetitive, onerous, and manual effort.

¹ This feature is planned for a future release and is not included in the current release

Unlock the Value of Serialization Data Across the Enterprise

Your serialization data is a gold mine you can tap for benefits beyond compliance. SPI is a self-service analytical application that opens previously unavailable opportunities. Everyone wins. For example, visibility into your serialized inventory data can help Sales release products faster and assist External Supply in CMO compliance and production monitoring. With SPI, you can help your enterprise improve customer service and patient care, reduce inventory, and lower supply chain costs.

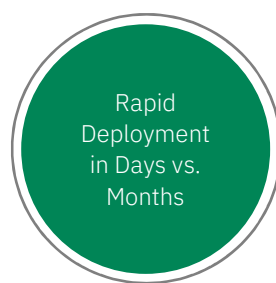


SPI Capabilities for Actionable Intelligence

SPI offers you the first step to leverage data as a foundation for using more advanced technologies to predict and prevent business problems before they happen. Build upon your serialization investment by unlocking the value of serialization data across your enterprise.

Unique Value of Serialized Product Intelligence

SPI is powered by a sophisticated analytical data model built on TraceLink's massively scalable Opus Digital Network Platform™, giving you solutions to quickly aggregate and analyze serialization data and shift from a reactive to a proactive serialized supply chain. SPI brings you scalability, high performance, and continuous innovation resulting from TraceLink's extensive customer base. SPI is validated and ready for GxP compliance. Importantly, your onboarding will take minimal effort and proceed at fast pace.



Unique Value of Serialized Product Intelligence

Shift from a Reactive to a Proactive Serialized Supply Chain

SPI can help you to establish actionable intelligence for your serialized drug supply chain and unlock the value of your serialization data across your enterprise. Proactively monitor your serialized drug supply chain, accelerate resolution of inconsistencies, and strive for timely product delivery to the market with SPI.

Contact Us

For more information about TraceLink visit [TraceLink.com](https://www.tracelink.com) or call +1 (781) 914-4900



KEY BENEFITS

- Get fast answers to critical business questions
- Enable self-service for stakeholders
- Minimize supply chain disruptions that affect shipments and revenue
- Speed up suspect product investigations
- Reduce time-consuming, error-prone manual reporting processes
- Support on-going regulatory compliance and reduce the risk of fines
- Safeguard the legitimacy of your pharmaceutical products

KEY FEATURES

- Centralized single source of truth for all users
- Always-on, high-performance big data architecture with massive scalability
- Ability to access and analyze serialization data at various levels of granularity
- Exception management, alerts, and root cause analysis
- End-to-end visibility into events involving multiple trading partners and systems
- Fully automated and continuous intelligence
- Rich, robust analytical model
- Access audit trails of all user operations